IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED, et al., Defendants.	C.A. No. 19-078 (RGA) CONSOLIDATED **PUBLIC VERSION: FILED 11/2/21**

LETTER TO THE HONORABLE RICHARD G. ANDREWS FROM STEPHEN B. BRAUERMAN IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE

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Dear Judge Andrews,

Plaintiffs' request to introduce new evidence into this action on the eve of trial should be denied. First, supplementation of an expert report must be "substantially justified or harmless," and Plaintiffs' proposed supplementation is neither. *See TQ Delta LLC v. 2Wire, Inc.*, Civil Action No. 13-1835-RGA, 2019 WL 1529952, at *1 (D. Del. Apr. 9, 2019). Plaintiffs are not substantially justified in their attempt to add to the case a publication which, at best, has marginal relevance to any issue in this proceeding and which was publicly available since at least August 2021, much less a new expert report addressing that publication. Second, granting Plaintiffs' request is not harmless and will significantly prejudice Defendant Sandoz, Inc. ("Sandoz"), who would not have an opportunity to question Dr. Nathan prior to trial on this new reference nor evaluate this new reference with its own expert witnesses. Requiring Sandoz to engage in these activities now, less than a week before the commencement of trial—particularly when they could have been addressed in August—will also prejudice Sandoz by diverting valuable resources for trial to address an irrelevant distraction. Plaintiffs' motion should be denied.

Rule 26(e) under the Federal Rules of Civil Procedure permits the supplementation of expert reports *prior* to pretrial disclosures. FED. R. CIV. P. 26(e). Here, pretrial disclosures have already taken place in the case, and expert discovery closed on August 18, 2021, with final expert reports due by June 18, 2021. The parties are now set to appear for trial in a week. Plaintiffs erroneously contend that good cause exists for their untimely disclosure of a new reference, Reis et al., *Effect of early treatment with fluvoxamine on risk emergency care and hospitalization among patients with COVID-19: the TOGETHER randomized, platform clinical trial*, LANCET GLOB. HEALTH 2021 (Pls. Ltr. to J. Andrews, Ex. A), identified by Plaintiffs as PTX 463, and their proposed service of a new expert witness report addressing that publication. "Good cause" is not the appropriate legal standard,[1] and, under the appropriate legal standard, Plaintiffs' decision to supplement its expert disclosures is not "substantially justified or harmless" and should be denied. *See TQ Delta*, 2019 WL 1529952, at *1.

First, the article that Plaintiffs seek to introduce into evidence is a publication that Plaintiffs admit was publicly available as early as August 2021, but that they failed to raise until now, days before trial. That fact alone permits denial of their request. *See Chase Manhattan Mortg. Corp. v. Advanta Corp.*, No. CIV.A. 01-507 (KAJ), 2004 WL 912949, at *1 n.1 (D. Del. Apr. 22, 2004) ("Advanta clearly had the opportunity months ago to obtain the supplemental report, serve it on its opponent, make the expert available for deposition, and apply to the court separately with a motion to allow the use of the supplemental report in this case. It chose to do none of those things, until the eve of trial."). That Plaintiffs may not have been aware of the reference earlier does not cure Plaintiffs' delay. *Id*. at *1. Nonetheless, in an effort to explain the delay, Plaintiffs make the extraordinary claim that the paper was not "available" because it had not been "peer-reviewed." But that does not justify this late disclosure; there is no requirement that experts rely only on peer-reviewed publications to offer opinions, nor any gate-keeping issue for admitting an otherwise published document into evidence on the basis that it

[1] Even if "good cause" were the appropriate standard to apply, no such good cause exists given the highly prejudicial and untimely nature of Plaintiffs' disclosure of supplemental expert opinions a week before trial.

was not "peer-reviewed." Plaintiffs raise peer review as a pretense for their failure to timely identify the document when it did become publicly available, by at least as early as August 2021.

Furthermore, supplementation here is not substantially justified as the publication Plaintiffs seek to bring into this proceeding is irrelevant to the infringement issues being litigated. One family of patents Plaintiffs assert claims methods of managing pirfenidone treatment of idiopathic pulmonary fibrosis ("IPF") in the very small (or nonexistent) population of patients that may also be taking fluvoxamine, an antidepressant approved for the treatment of obsessive compulsive disorder. *See* U.S. Patent Nos. 7,816,383, claim 6; 8,103,002, claims 3 and 9. To prove that Sandoz will induce infringement of those claims, Plaintiffs must prove that Sandoz's proposed package insert will induce doctors to practice the claimed methods (induced infringement), and that doctors will in fact practice those methods (direct infringement). Plaintiffs cannot prove either prong of inducement. With respect to direct infringement, as Sandoz will show at trial, Plaintiffs have failed to adduce any evidence that doctors practice the claimed methods of administering pirfenidone to patients in need of fluvoxamine by either discontinuing fluvoxamine or adjusting the dose of pirfenidone. Indeed, their only pulmonologist expert addressing infringement testified unequivocally that [redacted] Moreover, there is also no evidence that [redacted]

Recognizing this absence of proof, Plaintiffs apparently now seek to rely on evidence, in the form of PTX 463, that a clinical trial involving fluvoxamine for the treatment of COVID-19 has provided "significant" results. But this article does not provide relevant evidence of infringement: it does not address treatment of IPF, it does not address pirfenidone, nor does it address use of pirfenidone in the treatment of patients taking fluvoxamine or any method that would at all bear on the issues in this action. The reference does not even conclude with any certainty that fluvoxamine will in fact be used in treating COVID-19.

Indeed, the fact that this study was commenced years after Sandoz filed the ANDAs that are the subject of this litigation, in and of itself, demonstrates its irrelevance. Given that the COVID-19 pandemic began well-after Sandoz submitted its ANDAs including its proposed package inserts for pirfenidone, Sandoz could not have intended to induce doctors to infringe the asserted claims on the basis of this later-published article discussing the hypothetical treatment of COVID-19 with fluvoxamine. Stated otherwise, even if Plaintiffs can prove that, based on data in this article, some doctors would treat COVID-19 patients with fluvoxamine (which is doubtful), and even if Plaintiffs could further prove that some of those patients would also have IPF, and that some of those patients would be treated with pirfenidone, and that in doing so, some doctors would practice the claimed methods, Sandoz could not intend to induce that string of conduct. It strains credulity to argue that Sandoz could have intended anything with respect to the treatment of a virus causing a global pandemic that no one anticipated. There is simply no

reason to deviate from the ordinary discovery and trial rules to permit Plaintiffs to belatedly introduce this new publication and new expert report.

Not only is there no justification supporting Plaintiffs' request—let alone a substantial one—Sandoz will be prejudiced by allowing Plaintiffs to rely on new evidence at this late stage of the proceeding. *See, e.g.*, *Chase*, 2004 WL 912949 at *1 (denying supplemental reports filed one month before trial); *St. Clair Intell. Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co.*, No. CA 04-1436-LPS, 2012 WL 1015993, at *8 (D. Del. Mar. 26, 2012) (denying additional depositions and briefing as it would delay the setting of a new trial date); *In re TMI Litig.*, 193 F.3d 613, 721–22 (3d Cir. 1999) (belatedly-filed expert reports were excluded because "the rigorous pre-trial schedule" would preclude defendants "from having sufficient time to prepare to cross-examine on the late-filed reports"). Trial commences in one week. Permitting Plaintiffs to rely on a new reference that Sandoz's experts have not had a chance to review and on which to provide their own opinions will prejudice Sandoz, who is in the final stages of its own trial preparation. Moreover, permitting Plaintiffs to serve yet another expert report from Dr. Nathan addressing this publication would compound such prejudice, as Sandoz has not been permitted to examine Dr. Nathan on new opinions before trial. Plaintiffs make the tenuous claim that, in relying on that publication, Dr. Nathan will not provide any new opinions. If that is true, then Plaintiffs should not be allowed to introduce this new reference, let alone a new report by Dr. Nathan, as it is merely cumulative of what Dr. Nathan previously stated in his supplemental report. *See Robocast, Inc. v. Apple, Inc.*, No. CV 11-235 (RGA), 2013 WL 7118691, at *2 (D. Del. Dec. 4, 2013) ("The plaintiff's rationale for not striking the Hoffman supplemental report, that his clarification does not change the expert's previous opinion, is self-defeating. If the additional report doesn't change anything, then it's not necessary."). In any event, the fact that Plaintiffs seek to offer a new report from Dr. Nathan addressing this publication plainly suggests he will, in fact, have new opinions. Even a statement from Dr. Nathan that this publication supports his prior views will prejudice Sandoz, as Sandoz cannot depose Dr. Nathan prior to trial on the merits of the study described in the article.

In sum, the limited, if any, relevance of this publication and new expert opinions is outweighed by the prejudice to Sandoz from being sandbagged with this supplementation on the eve of trial, especially in view of the fact that this publication has been available publicly in some format since August 2021. Plaintiffs' request for leave should be denied.

Respectfully,

/s/ Stephen B. Brauerman

Stephen B. Brauerman (#4952)

Attachments

cc: All Counsel of Record (via electronic mail; w/attachments)